REMARKS

Claims 1-4, 6-14, 16, 18-19, 25-26 and 37-42 are pending in this application, of which claims 1-3, 7, 18-19, 25-26, 37-38 and 42 are currently amended, claims 4, 9, 14, 16, 26 and 40 are currently withdrawn from examination pursuant to a previous election, but are to be reinstated and allowed upon allowance of a respective generic (and any intervening) claim from which the respective withdrawn claim depends. Claims 5, 15, 17, 20-24, 27-36 are cancelled. Based on the foregoing amendments and following remarks, reconsideration and allowance of the application is respectfully requested.

Information Disclosure Statement

A supplemental information disclosure statement including the prosecution history, namely office actions and responses, of related US Patent Application S.N. 10/669,543. Applicant respectfully requests consideration of the references cited in the information disclosure statement.

Claim Rejections - 35 U.S.C. §103

Claims 1-3, 6-8, 10-13, 37 and 39-42 stand rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over U.S. Patent No. 5,853,418 ("Ken") in view of U.S. Patent No. 5,108,407 ("Geremia") and in further view of U.S. Patent No. 6,280,457 ("Wallace"). In particular, the Examiner has asserted that, in view of Geremia and further view of Wallace, it would have been obvious to one skilled in the art to construct the coil device described in Ken with a bioactive agent that is release or activated from the rest of the device when the device is heated to release the coil from the delivery catheter. Applicant respectfully disagrees in view of the amended claims.

The Supreme Court has recently addressed the issue of obviousness in KSR International vs. Teleflex Inc., 550 U.S. ___ (2007), in which the Court reiterated the requirement that a rejection on "obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness" (KSR at page 14 of the slip opinion), and further that a "fact finder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex parte reasoning. (KSR at page 17 of the slip opinion). While not specifically addressed by the Supreme Court in KSR, the prior art reference (or references when combined) must teach or suggest all the claim limitations (See MPEP §2143).

Independent claims 1, 37, and 42 each have been amended to recite a first material which, if the device is detached from a delivery catheter and implanted at a treatment site, may be heated by application of energy transmitted by an energy emitting element located external to the patient, and a bioactive agent (claims 1 and 37) or second material (claim 42) which, if the device is detached from a delivery catheter and implanted at a treatment site, is released (claim 1) or activated (claim 37) or partially melt or fuse together (claim 42) from the device upon heating the device by application of energy transmitted by said external energy emitting element.

Ken discloses releasing a vaso-occlusive coil in a treatment site using a well-known electrolytically severable joint (Col 6, lines 38-62). Geremia discloses releasing a vaso-occlusive coil into the treatment site by heating an adhesive bond that joins the coil to the delivery device (Col 4, lines 14-15). Even if Geremia may be properly combined with Ken, such combination would still not teach or suggest that the **coil** of Ken would be made of a

material that acts as a heating member after the device is detached from a delivery catheter and implanted in a treatment site in the patient's vasculature by application of energy transmitted by an energy emitting element located external to the patient. Both of these references disclose releasing a coil from a delivery device by detaching a severable joint; **neither reference discloses or suggests heating the already detached and implanted** coil application of energy transmitted by an energy emitting element located external to the patient, as recited in independent claims 1, 37 and 42. More particularly, the application of electricity or heat as disclosed in Ken and Geremia respectively, is to a severable ***joint*** that ***releases the coil*** from a delivery device into the treatment site and **not** to the coil itself to release or activate bioactive agents (claims 1 and 37) or partially melt and fuse together second material (claim 42) after the coil is detached from a delivery catheter, as recited in amended independent.

It was stated in the office action that, in view of Geremia and further view of Wallace, it would have been obvious to *"detach the coil from the device by heating and braking* (sic) *an adhesive bond between the coil itself and the rest of the device…and as further taught by Wallace et al., to provide the coil with a polymeric coating having a bioactive agent in order to improve the vaso-occlusion treatment"* (Emphasis added). As indicated in the disclosure of Geremia, the reason to apply heat to its occlusion device is to detach the coil from the pusher wire by breaking the adhesive bond. Wallace discloses a vaso-occlusive device comprising an inner core covered with a polymeric fiber, wherein the polymeric fiber covering may be used as a carrier for bioactive molecules (Col 12, lines 4-14). There is no reason to continue heating the device of Geremia after the coil is detached, as recited in independent claims 1, 37, and 42, even if combined with Wallace, because there is no

disclosure in Wallace that the bioactive agent carried by its device of Wallace is released or activated by heat. Wallace does not teach or suggest that the bioactive agent may be released or activated from the polymer device into the treatment site by the application of energy transmitted by an energy emitting element located external to the patient to heat the device after the device has been detached from a delivery catheter and implanted at the treatment site. Nor does Wallace teach or suggest melting and fusing the material to stabilize the vaso-occlusive device.

Even if a person skilled in the art would consider modifying the device of Ken, in view of Geremia and in further view of Wallace, the resulting device would be of an occlusion coil comprising bioactive agents that maybe detachable from a pusher wire by the application of heat, but not having the bioactive agent being activated or released by heating after the device is detached. The combination of cited references would not render the results of all the claims limitations of independent claims 1, 37, and 42, absent hindsight in view of the present application.

For at least these reasons, Applicant respectfully submits that independent claims 1, 37 and 42, as well as claims 2-3, 6-8, 10-13, and 39-41 which depend therefrom, are allowed over Ken, Geremia and Wallace, and requests withdrawal of the §103 claim rejections.

Additionally, claims 7, 18, 19, 25 and 38 stand rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Ken in view of Geremia, in further view of U.S. Patent Wallace and *in still further view* of U.S. Patent No. 6,059,815 ("Lee"), a combination of four separate references. In particular, the Examiner has stated that, in view of Geremia, in further view of Wallace, and in still further view of Lee, it would have been obvious to one

skilled in the art to construct the coil device described in Ken comprising a highly resistive or ferrous material with a bioactive agent that is detached from the rest of the device by RF and magnetic inducing heating. Applicant respectfully disagrees.

As demonstrated above, neither Geremia nor Wallace may be properly combined with Ken to result in the presently claimed invention, and there is no reason other than hindsight to further combine Lee. Lee discloses an aneurysm occlusion device that is released by laser, RF or magnetic inductive heating, which, again, ***releases the coil*** from the delivery device into the treatment site. However, claims 7, 18, 19 and 25 recite the ***release of a bioactive agent***, and claim 38 recites the ***activation*** of a bioactive agent, upon magnetically inducing heating of the device ***after the device is detached from a delivery catheter and it is implanted*** at the treatment site. Furthermore, neither of the cited references suggests applying magnetically inducing heating to the device after the detachment from the delivery catheter is performed to then, release or activate bioactive agents, absent hindsight in view of the present application.

Magnetic resonance imaging systems are used for imaging of a body and they are not normally used to produce heat in a body, since the production of heat in a body when undergoing an MRI is known as an undesirable and potentially dangerous side effect if the body contains certain amount of highly resistive material. A person skilled in the art would not normally look to using an MRI system for heating an implanted device. Therefore, there is no reason, absent hindsight, to combine the cited references to heat an implanted device using an MRI system to activate or release a bioactive agent as recited in claims 7, 18, 19 and 25.

For at least these reasons, Applicant respectfully submits that independent claims 7, 18, 19, 25 and 38, are allowed over Ken, Geremia, Wallace and Lee, and requests withdrawal of the §103 claim rejections.

CONCLUSION

In view of the foregoing amendments and remarks, Applicant respectfully submits that all pending claims are allowable over the cited references. Accordingly, a notice of allowance is earnestly solicited. If the Examiner believes that a further telephone interview could expedite resolution of any remaining issues, he is welcome to call the undersigned at the below-listed number.

Respectfully submitted,
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